11) Publication number:

0 328 055 B1

(12)

EUROPEAN PATENT SPECIFICATION

- (4) Date of publication of patent specification: 11.11.92 (5) Int. Cl.5: A61J 9/00
- (1) Application number: 89102122.2
- ② Date of filing: 08.02.89
- 9 Pre-filled nurser pouch.
- 3 Priority: 12.02.88 US 155468
- 43 Date of publication of application: 16.08.89 Bulletin 89/33
- Publication of the grant of the patent: 11.11.92 Bulletin 92/46
- Designated Contracting States:
 BE DE FR IT
- References cited:
 WO-A-85/04574
 US-A- 4 629 080
 US-A- 4 640 425

3 Proprietor: ABBOTT LABORATORIES

Abbott Park, Illinois 60064(US)

- ② Inventor: McCoy, Ned R. 6747 Willow Grove Place Dublin Ohio 43017(US) Inventor: Lierman, James C. 4863 Inisheer Court Dublin Ohio 43017(US)
- Representative: Modiano, Guido et al c/o Modiano & Associati S.r.l. Via Meravigli,
 16
 I-20123 Milano(IT)

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

10

15

20

30

40

45

50

55

Description

Background of the Invention

There are currently present on the market several infant nurser kits which include a supply of empty, clear plastic bags, some of which may be interconnected by perforations and formed in a roll. The bag must be carefully inserted into a suitable sleeve-like shell or holder, the upper edge of the bag being folded over the upper edge of the holder. The bag must then be filled with previously purchased infant formula or other pediatric liquids, after which a nursing nipple/retainer assembly is threadably mounted thereon. Surveys indicate that 40 - 50% of new mothers in the United States of America use such "disposable bottles" in feeding their infants and older babies and that an average of five such "disposables" are used per day. One possible problem with this current practice is that storage must be provided for both the bags and the premixed formula, the latter of which is often in the form of unwieldy cases of cans or glass bottles, and that, therefore, one might understandably run out of one or the other, which could result in the infant or older baby not being fed on schedule. Further, several separate, rather intricate steps are required, each of which has to be undertaken with extreme care to ensure against contamination of whatever pediatric nutritional is to be given to the infant or older baby.

1

Known from WO-A-85/04,574 is a disposable container as defined in the precharacterizing part of claim 1. The container includes a collapsible pouch having a feeding unit of nursing formula sealed within the pouch and a nurser nipple sealed onto the outside surface of the pouch. However, this known pouch incurs the expense of an incorporated nursing nipple and requires a special holder structure for containing the one-piece pouch/nipple assembly. Therefore, it cannot be used with widely used conventional nursers having a sleeve-like holder and a conventional nursing nipple which screws onto the upper end thereof.

Also known from US-A-4,640,425 is a one-piece nursing container made from a single web of flexible material having a nursing nipple attached thereto. The contents of the container and the nipple are separated and maintained in a sterile condition by the walls of the single web container until use. The portion of the single web enclosing the nursing nipple is removable for gaining access to the nipple. However, the pouch known from US-A-4,640,425 incurs the expense of an incorporated nursing nipple and is awkward to handle. Therefore, it cannot be employed with widely used conventional nursers having a sleeve-like holder and a conventional screw-on nursing nipple which screws

onto the upper end of the nurser.

SUMMARY OF THE INVENTION

The problems encountered in the use of the known pre-filled nurser pouches are overcome by an aseptically pre-filled pouch of pediatric nutritional or the like as defined in the appended claims.

The present invention is directed to a flexible, clear plastic disposable pouch which has been aseptically filled with infant formula or other pediatric nutritional and immediately sealed in a commercially sterile environment to prevent contamination thereof. In that these single-serving prefilled pouches are aseptically filled with suitable formulations of pediatric nutritionals, they have an excellent non-refrigerated shelf stability. Further, such pouches may also be aseptically pre-filled with sterilized water, glucose water, juices, etc.

The pouches themselves are formed out of a suitable multi-layered clear plastic material which provides both good oxygen and water barrier characteristics as well as high resistance to puncturing.

The unique shape of the subject pre-filled pouch is such that it allows easy entry thereof into any one of several suitable sleeve-like holders adapted to have a nursing nipple assembled thereon. The upper edge of each pre-filled pouch is notched to facilitate opening thereof after insertion of the pouch into a suitable nursing holder.

Still further, the subject pre-filled, singleserving nurser pouch is lightweight and convenient to shop for and store, being flexible, unbulky, very portable and requiring no refrigeration. The subject pre-filled pouches, which may be printed with volumetric graduations, also permits the purchaser/user to view the contents thereof through the clear plastic material and also permits convenient heating of the contents prior to opening of the pouch by simply dropping the sealed pouch into a pan of heated water or holding it under a faucet of warm running water.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front elevational view of an aseptically pre-filled pouch for a nurser embodying the present invention;

FIG. 2 is a side elevational view thereof as viewed from either side:

FIG. 3 is a top plan view thereof;

FIG. 4 is a front elevational view of the pre filled pouch of FIGS. 1-3 as same is about to be inserted into a sleeve-like holder which is shown partially in vertical section;

FIG. 5 is a front elevational view after insertion of the pouch into the holder and as the pouch is

15

25

30

40

50

being opened;

FIG. 6 is a front elevational view after the pouch has been opened and the top portion thereof folded over the upper edge of the holder but prior to assembly of the nursing nipple thereon; and

FIG. 7 is an enlarged fragmentary transverse sectional view taken through the plastic film from which the pre-filled pouch of the present invention is formed and illustrating the multi-layer structure thereof.

DESCRIPTION OF THE PREFERRED EMBODI-MENT

Referring now to the drawings a preferred form of an aseptically pre-filled pouch 10 for an infant or baby nurser is shown in FIGS. 1-3. The pouch 10 is formed from a roll of multi-layered plastic film material which is strong and puncture-resistant and has excellent oxygen and water barrier characteristics, as will be described more fully hereinafter. The film material is sterilized, formed, and filled with either sterilized water, glucose water, juices or pre-mixed formulas or other suitable pediatric nutritionals such as Ross Laboratories' Similac, Isomil, Pedialyte, etc., and then sealed in a commercially sterile environment to provide a convenient, portable, lightweight, single-serving package which has excellent shelf-life stability without refrigeration. The pre-filled pouch 10, being clear whereby the contents are visible to the purchaser/user, is flexible, easily stored, and permits easy warming of the contents by either placing the unopened pouch 10 in a pan of heated water or by holding the pouch 10 under a faucet of warm running water. Although not shown in the drawings, the clear plastic pouches 10 may be printed with volumetric graduations. The pouch 10 may be aseptically formed, filled and sealed in one operation in a manner such that non-contamination of the contents is ensured.

The pre-filled pouch 10 is characterized by heat-sealed side edges 12, by a heat-sealed or folded top edge 14, and by a heat-sealed or folded bottom edge 16. The upper portion of the side edges 12 of the pre-filled pouch 10 diverge in an upward direction, as at 18 in FIG. 1, to facilitate handling the pouch 10 and to provide sufficient pouch material to be folded downwardly over an upper edge 20 of a suitable sleeve-like cylindrical holder 22 after opening of the pouch 10, as illustrated in FIG. 6. As best illustrated in FIGS. 4, 5 and 6, the disposable pre-filled pouch 10 is adapted to be inserted into either the top or the bottom of the sleeve-like holder 22 which is of a known type having external threads 24 provided on its upper end for threadably receiving thereon a nursing nipple and threaded retainer assembly 26, as illustrated in FIG. 6. Although not shown in the drawings, some holders may have a reverse taper wherein the circumference at the lower end is slightly greater than at the upper end.

As best illustrated in FIG. 4, the lower portion of the side edges 12 of the pouch 10 may converge in a downward direction, as at 28, to facilitate downward entry of the pre-filled pouch 10 into the holder 22. Engagement of the side edges 12 with the inner surface of the holder 22 tends to round out the main body portion of the pre-filled pouch 10 from its normal generally elliptical shape, which is best illustrated in FIG. 3, whereby the pouch 10 fits snugly within the cylindrical holder 22.

A V-shaped notch 30 is provided in one of the side edges 12 of the pre-filled pouch 10 just below the sealed top edge 14 thereof to facilitate tearing off the top edge 14 to open the pouch 10 after the pre-filled pouch 10 has been inserted into the holder 22, as best illustrated in FIG. 5. Preferably, a second V-shaped back-up notch 30a is provided in the opposite side edge 12, as insurance should the notch 30 not function correctly to open the upper end of the pre-filled pouch 10. A relatively linear tear from the notch 30 (or back-up notch 30a) is made possible by using unidirectionally oriented plastic film material. As the maximum fill level for the pre-filled pouch 10 is indicated by the broken line 34, it is evident that, after the top edge 14 has been removed, there is sufficient pouch material to be folded over the upper edge 20 of the holder 22 and to overlap the holder threads 24 without spilling the contents of the pre-filled pouch 10. As the basic structure and shape of the pre-filled pouch 10 are of importance as noted herein, so is the specific multi-layered structure of the clear plastic film material from which the pre-filled pouch 10 is formed. Although it is obvious that this film material must be strong and puncture resistant, it must also provide excellent oxygen and water barrier characteristics. As illustrated in FIG. 8, one such film structure is characterized by a five layer co-extrusion 36 including an inner layer of clear plastic 38 having excellent oxygen barrier characteristics, layers of suitable adhesive 40 and 42 on opposite surfaces thereof to each of which is laminated a layer of clear plastic 44 and 46, respectively, having excellent water barrier characteristics. The layer 44 serves as the inner surface of the pre-filled pouch 10 which is exposed to the product contained within the pouch 10. Laminated to the other layer 46 by means of a thin layer of adhesive 48 is a layer 50 of clear plastic which has excellent puncture-resistant properties and which therefore serves as the outer side surface of the pre-filled pouch 10. Other multi-layer clear plastic film materials may prove to be equally or even more

15

20

30

40

effective.

The fact that the subject pre-filled pouch 10 has excellent shelf-life stability without refrigeration is a result of the aseptic filling of the product, packaging barrier properties and, in some instances, product reformulation.

The convenience, reliability and safety features of this infant/baby feeding advance are believed quite obvious. Compared to the current practice of the mother finding an empty disposable nurser bag, then hopefully finding a can of the product to be fed to the infant, opening the bag and inserting the limp bag into a holder and then opening the can of the product and carefully emptying it into the bag while doing her best to ensure against contamination of the product, the advance disclosed herein is much simpler and requires many fewer steps with insurance against contamination being assured. The mother simply picks up the single-serving pre-filled pouch 10 disclosed herein, inserts it into the holder (after warming it as described herein, if desired), pulls off the top of the pouch 10, folds over the excess pouch material, and then assembles the nipple/retainer ring 26.

While there has been shown and described a preferred embodiment of the invention, it will be obvious to those skilled in the art that changes and modifications may be made without departing from the invention, and it is intended by the appended claims to cover all such changes and modifications as fall within the true spirit and scope of the invention.

Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly, such reference signs do not have any limiting effect on the scope of each element identified by way of example by such reference signs.

Claims

An aseptically pre-filled pouch of pediatric nutritional or the like comprising a clear plastic film material (36) which is sterilized, formed, aseptically filled, and aseptically sealed to provide a pre-filled pouch (10) having sealed side, top and bottom edges (12, 14, 16), said plastic film material (36) is a multi-layer material (36) having excellent oxygen and water barrier properties such that, when combined with the aseptic filling, said material imparts excellent shelf-life properties without refrigeration, characterized in that said sealed side edges (12) have lower portions (28) which converge in a downward direction whereby to facilitate downward insertion of said pouch (10) into a sleevelike holder (22) of the type adapted to have a nursing nipple (26) assembled on the upper end (20) thereof, and upper portions (18) which diverge in an upward direction whereby to provide sufficient plastic film material (36) to be folded downwardly over the upper edge (20) of a sleeve-like holder (22) upon opening of said pouch (10) with said pouch (10) disposed in said holder (22) at least one of said sealed side edges (12) being provided with a V-shaped notch (30) just below said sealed top edge (14) to facilitate opening of said pouch (10).

- An aseptically pre-filled pouch according to claim 1, characterized in that said clear plastic film material (36) comprises a multi-layer coextrusion (38, 40, 42, 44, 46, 48, 50).
- 3. An aseptically pre-filled pouch according to claims 1 and 2, characterized in that said multi-layer co-extrusion (38, 40, 42, 44, 46, 48, 50) further comprises an oxygen barrier layer (38), adhesive layers (40, 42) provided on opposite surfaces of said oxygen barrier, a water barrier layer (44, 46) laminated on each of said adhesive layers (40, 42), a further adhesive layer (48) provided on one of said water barrier layers (44, 46), and a puncture resistant outer layer (50) provided on said further adhesive layer (48).
- 4. An aseptically pre-filled pouch according to claim 1 and 2 or 3, characterized in that it further comprises a second back-up-V-shaped notch (30a) formed in the other one of said side edges (12).
- 5. An aseptically pre-filled pouch according to claim 1, characterized in that it comprises a linear tear line extending from the V-shaped notch (30) to the second V-shaped notch (30a), said linear tear line being made of unidirectionally oriented plastic film material.
- 6. An aseptically pre-filled pouch according to one or more of the preceding claims, characterized in that it is insertable either upwardly or downwardly into a sleeve-like holder (22), said pouch (10) being openable upon tearing said multi-layer material (36) at said V-shaped notch, said upper diverging portion (18) being foldable downwardly over an upper edge (20) of a conventional holder (22), to overlap the threads thereof, prior to assembly of a conventional nursing nipple (26) on the upper end (20) of such conventional holder.

Patentansprüche

20

25

30

1. Steril vorgefüllter Beutel für eine pädiatrische Nahrung oder ähnlichem, mit einem durchsichtigen Kunststoff-Schichtmaterial (36), der sterilisiert, ausgeformt und keimfrei gefüllt ist und keimfrei verschlossen ist, um einen vorgefüllten Beutel (10) mit dichten Seitenkanten, oberen Kanten und Bodenkanten (12, 14, 16) vorzusehen, wobei das Kunststoff-Schichtmaterial (36) aus einem vielschichtigen Material (36) mit ausgezeichneten Abschirmeigenschaften gegnüber Sauerstoff und Wasser besteht, derart, daß dann, wenn eine Verbindung mit der keimfreien Füllung erfolgt, dieses Material ausgezeichnete Haltbarkeitseigenschaften ohne Kühlhaltung gewährleistet,

dadurch gekennzeichnet, daß die abgedichteten Seiten, Kanten und Ränder (12) untere Abschnitte (28) aufweisen, die nach unten hin konvergieren, um dadurch ein nach unten erfolgendes Einschieben des Beutels (10) in einen hülsenförmigen Halter (22) des Typs zu vereinfachen, bei dem ein Still-Nippel (26) an seinem oberen Ende (20) angeordnet werden kann, und obere Abschnitte (18) aufweist, die nach oben zu divergieren, wobei ausreichend Kunststoff-Schichtmaterial (26) vorhanden ist, um dieses über den oberen Rand (20) eines hülsenförmigen Halters (22) nach unten zu falten, und zwar nach dem Öffnen des Beutels (10), wobei der Beutel (10) in dem Halter (22) angeordnet ist und wobei wenigstens einer der abgedichteten Seitenränder (12) mit einer Vförmigen Kerbe (30) versehen ist, und zwar unmittelbar unterhalb dem abgedichteten oberen Rand (14), um dadurch das Öffnen des Beutels (10) zu vereinfachen.

- Steril vorgefüllter Beutel nach Anspruch 1, dadurch gekennzeichnet, daß das durchsichtige Kunststoff-Schichtmaterial (36) aus einem vielschichtigen Koextrusionsmaterial (38, 40, 42, 44, 46. 48. 50) besteht.
- Steril vorgefüllter Beutel nach Anspruch 1 und 2, dadurch gekennzeichnet, daß das vielschichtige Koextrusionsmaterial (38, 40, 42, 44, 46, 48, 50) ferner eine Sauerstoff-Sperrschicht (38) aufweist, daß ferner auf sich gegenüberliegenden Flächen der Sauerstoff-Sperrschicht Klebemittelschichten (40, 42) vorgesehen sind, daß auf jeder der Klebemittelschichten (40, 42) eine Wasser-Sperrschicht (44, 46) auflaminiert ist, daß ferner eine Klebemittelschicht (48) auf einer der Wassersperrschichten (44, 46) vorgesehen ist und daß eine gegenüber einem Durchstechen widerstandsfähige äußere Schicht (50) auf der weiteren Klebemittel-

schicht (48) vorgesehen ist.

- 4. Keimfrei vorgefüllter Beutel nach Anspruch 1 und 2 oder 3, dadurch gekennzeichnet, daß er ferner eine zweite Unterstützungs-V-förmige Kerbe (30a) aufweist, die auf der anderen der Seitenkanten (12) ausgebildet ist.
- 5. Keimfrei vorgefüllter Beutel nach Anspruch 1, dadurch gekennzeichnet, daß er eine lineare Reißlinie aufweist, die sich von der V-förmigen Kerbe (30) zu der zweiten V-förmigen Kerbe (30a) erstreckt, wobei die lineare Reißlinie aus in einer Richtung orientiertem Kunststoff-Schichtmaterial hergestellt ist.
- 6. Keimfrei vorgefüllter Beutel nach einem oder mehreren der vorhergehenden Ansprüche, dadurch gekennzeichnet, daß der Beutel entweder nach oben oder nach unten in einen hülsenförmigen Halter (22) einschiebbar ist, daß der Beutel (10) geöffnet werden kann nachdem das vielschichtige Material (36) an der V-förmigen Kerbe aufgerissen wurde, wobei der obere divergierende Abschnitt (18) nach unten über den oberen Rand (20) eines herkömmlichen Halters (22) faltbar ist, derart, daß dieser die Gewinde des Halters überlappt und zwar vor der Anordnung eines herkömmlichen Still-Nippels (26) auf dem oberen Ende (20) eines derartigen herkömmlichen Halters.

Revendications

35 Poche pré-remplie, dans des conditions aseptiques, d'aliment pédiatrique ou analogue, constituée d'un matériau sous forme de film plastique transparent (36) qui est stérilisé, mis en forme, rempli sous conditions aseptiques, et scellé sous conditions aseptiques pour don-40 ner une poche préremplie (10) présentant un côté scellé, un bord supérieur et un bord inférieur (12, 14, 16), ledit matériau (36) sous forme de film plastique étant un matériau multicouche (36) présentant d'excellentes caracté-45 ristiques de barrière anti-oxygène et anti-humidité telles que, en combinaison avec le remplissage aseptique, ledit matériau donne d'excellentes caractéristiques de durée de stockage sans réfrigération, poche caractérisée par le 50 fait que lesdits bords latéraux scellés (12) présentent des portions inférieures (28) qui convergent en direction vers le bas, facilitant ainsi l'insertion, vers le bas, de ladite poche (10) dans un support (22) en forme de manchon du type conçu pour que l'on monte sur son extrémité supérieure (20) une tétine de biberon (26), ainsi que des portions supérieu-

15

30

40

45

50

res (8) qui divergent en direction vers le haut, permettant ainsi de replier vers le bas suffisamment de matériau sous forme de film plastique (36), par-dessus le bord supérieur (20) d'un support (22) en forme de manchon, lors de l'ouverture de ladite poche (10), ladite poche (10) étant disposée dans ledit support (22), au moins l'un desdits bords latéraux scellés (12) présentant une rainure en forme de V (30) juste en dessous desdits bords supérieurs scellés (14) pour faciliter l'ouverture de ladite poche (10).

Poche pré-remplie dans des conditions aseptiques, conformément à la revendication 1, caractérisée par le fait que ledit matériau sous forme de film plastique transparent (36) est constitué d'une co-extrusion multicouche (38, 40, 42, 44, 46, 48, 50).

3. Poche pré-remplie dans des conditions aseptiques, conformément aux revendications 1 et 2, caractérisée par le fait que ladite co-extrusion multicouche (38, 40, 42, 44, 46, 48, 50) est en outre constituée d'une couche (38) formant barrière antioxygène, de couches adhésives (40, 42) prévues sur les surfaces opposées de ladite barrière anti-oxygène, une couche (44, 46) formant barrière anti-humidité, stratifiée sur chacune desdites couches adhésives (40, 42), une autre couche adhésive (48) prévue sur l'une desdites couches (44, 46) formant barrière anti-humidité et une couche extérieure (50) résistant au poinçonnement et prévue sur ladite autre couche adhésive (48).

4. Poche préremplie dans des conditions aseptiques selon les revendications 1 et 2 ou 3, caractérisée par le fait qu'elle présente en outre une seconde encoche de secours (30a) en forme de V formée dans l'autre desdits bords latéraux (12).

5. Poche pré-remplie dans des conditions aseptiques selon la revendication 1, caractérisée par le fait qu'elle présente une ligne de déchirure linéaire s'étendant depuis l'encoche en forme de V (30a) jusqu'à la seconde encoche en forme de V (30a), ladite ligne de déchirure linéaire étant faite d'un matériau sous forme de film plastique d'orientation unidirectionnelle.

6. Poche pré-remplie dans des conditons aseptiques, selon une ou plusieurs des revendications précédentes, caractérisée par le fait qu'elle peut s'insérer, soit vers le haut, soit vers le bas, dans un support (22) en forme de manchon, ladite poche (10) pouvant s'ouvrir

lorsque l'on déchire ledit matériau multicouche (36) à ladite encoche en forme de V, ladite portion supérieure divergente (8) pouvant se replier, vers le bas, par-dessus un bord supérieur (20) d'un support conventionnel (22), pour en recouvrir le filetage, avant montage d'une tétine de biberon conventionnelle (26) sur l'extrémité supérieure (20) d'un tel support conventionnel.







